UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/172,990	10/14/98	OZENBERGER B	AHP-98126-bok

HM12/0401
AMERICAN HOME PRODUCTS CORPORATION
PATENT LAW DEPARTMENT 2B2
ONE CAMPUS DRIVE
PARSIPPANY NJ 07054

EXAMINER	
DUFFY,P	
ART UNIT	**PAPER NUMBER**
1645	4

DATE MAILED: 04/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	08/172,990	Ozenberger et al
	Examiner	Group Art Unit
	Duffy	1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-24 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other notice to comply i sequence rules.

Office Action Summary

DETAILED ACTION

Sequence Requirements

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Compliance with the sequence rules is required in response to this office action.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 11, drawn to polynucleotides, host cells and methods of producing the protein, classified in class 536, subclass 23.1.

II. Claims 6-10, drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 12, 13 and 20, drawn to methods of using the probes to detect the polynucleotide and diagnostic process therefore classified in class 435, subclass 6.

IV. Claims 14 and 15, drawn to antibodies, classified in class 530, subclass 387.1.

V. Claims 16-19, drawn to methods of using binding reagents to detect the presence of the polypeptide and diagnostic processes therefore, classified in class 435, subclass 7.1.

VI. Claims 21-22, drawn to methods of screening for agents which regulate the activity of the amyloid binding polypeptide, classified in class 435, subclass 7.21.

VII. Claim 23, drawn to method of treating disease by administering the polypeptide, classified in class 514, subclass 12.

VIII. Claim 24, drawn to a transgenic or chimeric animal, classified in class 800, subclass 13.

3. The inventions are distinct, each from the other because of the following reasons: Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide product can be used in methods of transformation of cells, in methods of gene therapy, in methods of *in situ* chromosome mapping and in methods of producing the protein product.

Inventions II and (VI or VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be labeled and used in a method of detection of antibodies or the polypeptides can be used as an immunogen to produce antibodies.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in a materially different process of using that product such as a therapeutic or as a means for purification of the polypeptide which it specifically binds.

Inventions I, II, IV and VIII are related as products. The claims of Group I are drawn to a polynucleotide, those of Group II are drawn to a polypeptide, that of Group IV to antibodies, and that of Group VIII to an chimeric or transgenic animal. The inventions can be shown to be distinct because they are made by different methods (e.g. recombinant production, in vitro chemical synthesis, Merrifiled synthesis, injection of an animal with the protein, or injection of the oocyte of an animal) and because they are physically (e.g. nucleic acids, amino acids, and animals) and functionally distinct chemical entities (e.g. encode proteins, mediate biological activity, mediate an immune response and genetically engineered animal as a model of disease). Thus, each product is distinct from each of the other products.

Inventions III, V, VI and VII are related as methods which use the distinct products as described *supra*. The methods are distinct each from the other because they utilize different reagents as defined by the products above, have different goals (e.g. detection of the polynucleic acid, detection of the protein, treatment of disease, screening for agents which regulate activity) and have different method steps and different final outcomes (e.g. detection/diagnosis of disease using polynucleotides or polypeptides, treatment of disease by providing polypeptide, identification of active regulatory agents. For the foregoing reasons each method is distinct from every other method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and in the absence of restriction would place an undue search and examination burden on the examiner, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Andrea Walsh on February 17, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

5. The time period for response for both the Sequence Requirements and the Restriction/Election is set to run concurrently. A complete response should respond to both the Sequence Requirements and the Restriction/Election.

6. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Patricia A. Duffy, Ph.D.
March 30, 1999

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600

Application No.: [redacted] 09/172,990

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Applicant should follow the format of the attached sample statement to request that the CRF filed in the parent application be used to create a CRF in this application.

Applicant Must Provide:

☐ An Initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An Initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

Sample Statement

Sample Request to Use Computer Readable Form from Another Application

The following paragraph, or language having the same effect, can be used to invoke the procedures of 37 CFR section 1.821(e) in which an identical computer readable form from another application is used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application:

> The computer readable form in this application, 08/100,000, is identical with that filed in Application Number 07/999,999, filed March 1, 1988. In accordance with 37 CFR 1.821(e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].